POST-TRIAL OBLIGATIONS

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POST-TRIAL OBLIGATIONS

1.1.Towards individual agents

1.1.1Obligations of access to care after research

a) Obligations of access to an intervention identified as beneficial in a study

b)Obligation of access to other appropriate care

1.1.2.Obligations of access to information after research

1.2.Towards collective agents

1.2.1Obligations of access to care after research

a) Obligations of access to an intervention identified as beneficial in a study

b) Obligation of access to other appropriate care

1.2.2.Obligations of access to information after research

[1]Mastroleo I. Developing World of Bioethics, 2015.

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HELSINKI DECLARATION

2000.	2008.	2013.
Article 30. At the conclusion of the study, every participant entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods inedited by the study.	Article 33. At the conclusion of the study, patients entered into the study are entitled to be informed about the outcome of the study and to share any benefits that result from it, for example access to interventions identified as beneficial in the study or other appropriate care or benefits.	Article 34. In advance of a clinical trial, sponsors, researchers and host country governments should make provisions for post-trial access for all participants who still need an intervention identified as beneficial in the trial. This information must also be disclosed to participants during the informed consent process.

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HELSINKI DECLARATION

2000.	2008.	2013.
- beneficial- by sound clinical evaluation, evidence of safety and efficacy What level of evidence is needed? Access to essential healthcare/ other appropriate care? Access to information? 2004 clarification -during study planning identified -described in the study protocol for RECs consideration	- participants entitled to be informed of the outcome of the study - other appropriate care - benefit sharing? Not specified for example beneficial intervention may be other things other care - negotiated by the participants, sponsors and community (Emanuel et al.)	- no more benefit sharing - information disclosure to participants in informed consent - RECs responsibility? Responsible for assurance of post trial access- sponsors, researchers, governments - no other appropriate care- because of the inducement of local leaders to pressure people to participate in studies

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FUTURE CONSIDERATIONS

- 1.1.Towards individual agents

1.1.1Obligations of access to care after research

- part of the protocol and explained in the informed consent
- REC should evaluate it and decide if there are provisos whether to continue or not
- responsible for assurance of post trial access- sponsors, researchers, governments

- a) Obligations of access to an intervention identified as beneficial in a study

- beneficial- by sound clinical evaluation, evidence of safety and efficacy

- b)Obligation of access to other appropriate care

- must be provided together with access to an intervention

- 1.1.2.Obligations of access to information after research

- must be provided

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FUTURE CONSIDERATIONS

- 1.2.Towards collective agents

1.2.1Obligations of access to care after research

-part of the protocol and explained in the informed consent

- REC should evaluate it and decide if there are provisos whether to continue or not
- responsible for assurance of post trial access- sponsors, researchers, governments

- a) Obligations of access to an intervention identified as beneficial in a study

-beneficial- by sound clinical evaluation, evidence of safety and efficacy

- b) Obligation of access to other appropriate care

- must be provided together with access to an intervention

- 1.2.2.Obligations of access to information after research

- must be provided

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FUTURE CONSIDERATIONS

- Role of REC-s

- methodology of the research

-benefit risk ratio

- quality of informed consent

BENEFICENCE- post-trial access is a part of beneficence risk ratio

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FUTURE CONSIDERATIONS

- SPONSORS- obligations of provisions
- COUNTRIES- importance of national regulation of this area
- INTRENATIONAL bodies- importance of reaffirmation of these obligations – global justice

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REFLECTION PAPER ON ETHICAL AND GCP ASPECTS OF CLINICAL TRIALS OF MEDICINAL PRODUCTS FOR HUMAN USE CONDUCTED OUTSIDE OF THE EU/EEA AND SUBMITTED IN MARKETING AUTHORIZATION APPLICATIONS TO THE EU REGULATORY AUTHORITIES, EMA

- Regulatory action/action plan:
- 1. The applicant for a marketing application authorization should provide EU Regulatory Authorities with a description of the situation of trial participants with regard to post trial access to treatment and medical care depending on their localization and the national or regional health care system. The applicant should describe the provisions made for post trial access to treatment and medical care for study participants depending on their localization and the treatment and medical care otherwise available. This information can form part of the clinical study report section on ethical considerations.
- 2. EU Regulatory Authorities should identify those studies that may give rise to special ethical concern regarding access to treatment post trial and where applicable to seek additional assurance that the solution was appropriate and ethically acceptable.
- 3. EU Regulatory Authorities will summarize this information in the Public Assessment report.

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- Regulatory action/action plan
- 1. EU Regulatory Authorities should develop a clear and detailed system for regulatory actions in case of non compliance with ethical and GCP requirements.
- 2. Where clear serious concerns are identify the EU Regulatory Authority should communicate these concerns to the National Regulatory Authority of the Country(ies) concerned.

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- Information and possible action by regulators of countries outside EU/EE
- Request for additional information or action by the sponsor
- Inspection or re-inspection
- Rejection of data/exclusion of trial/negative opinion
- Education and Facilitation
- Warning
- Transparency regarding clinical trial conduct and compliance including non-compliant Marketing

Authorizations

- Suspension of the Marketing Authorization/Urgent Safety restriction /Revocation of the Marketing Authorization
- Penalties

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DISCOURS ANALYISIS

- actors and participants of the discourse- sponsors, researchers, regulatory agencies, world organizations, governments, scientists (bioethicists)
- the energy that drives the discourse – rules and regulations, consensus, appeasement, issues of global justice
- attractors – world organizations, regulatory agencies, sponsors
- interpretative level of public discourse –ethical issues , legal issues, finical issues
- What did the community gain from the emergence and development of public discourse?
- debate sometimes solutions for implementation and consensus but on the level of individual societies not on a global level

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